



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0117]

Draft Guidance for Industry and Food and Drug Administration Staff; Providing Information About Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Draft Guidance for Industry and Food and Drug Administration Staff: Providing Information About Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug, and Cosmetic Act.” FDA is issuing this guidance document to describe how to compile and submit the readily available pediatric use information required under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by [INSERT

DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER],

(see the "Paperwork Reduction Act of 1995" section of this document).

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled “Draft Guidance for Industry and Food and Drug Administration Staff: Providing Information About Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug, and Cosmetic Act” to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

With regard to the guidance:

Sheila Brown,

Center for Devices and Radiological Health,

Food and Drug Administration,

10903 New Hampshire Ave.,
Bldg. 66, rm. 1651,
Silver Spring, MD 20993-0002,
301-796-6563; or
Stephen Ripley,
Center for Biologics Evaluation and Research (HFM-17),
Food and Drug Administration,
1401 Rockville Pike, suite 200N,
Rockville, MD 20852,
301-827-6210.

With regard to the proposed collection of information:

Daniel Gittleson,
Office of Information Management,
Food and Drug Administration,
1350 Piccard Dr.,
PI50-400B,
Rockville, MD 20850,
301-796-5156,
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I. Background

On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 (FDAAA)¹ (Public Law 110-85) amended the FD&C Act by adding, among other things, a new section 515A (21 U.S.C. 360e-1) of the FD&C Act. Section 515A(a) of the FD&C Act requires persons who submit certain medical device applications to include, if readily available:

1. A description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; and
2. The number of affected pediatric patients.

The purpose of this guidance document is to describe the type of information that FDA believes is readily available to the applicant, and the information FDA believes should be included in a submission to meet the requirements of section 515A(a) of the FD&C Act.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the requirements relating to the submission of information on pediatric subpopulations that suffer from the disease or condition that a device is intended to treat, diagnose, or cure. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

¹ Title III of FDAAA, which includes new section 515A, is also known as the Pediatric Medical Device Safety and Improvement Act of 2007.

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov> or from CBER at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>. To receive “Draft Guidance for Industry and Food and Drug Administration Staff: Providing Information About Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug, and Cosmetic Act,” you may either send an email request to ds mica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1801 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information that they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden on the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Devices; Pediatric Uses of Devices; Requirement for Submission of
Information on Pediatric Subpopulations That Suffer From a Disease or Condition that a
Device is Intended to Treat, Diagnose, or Cure

The draft guidance suggests that applicants who submit certain medical device applications include, if readily available, pediatric use information for diseases or conditions that the device is being used to treat, diagnose, or cure that are outside the device's approved or proposed indications for use, as well as an estimate of the number of pediatric patients with such diseases or conditions. The information submitted will allow FDA to identify pediatric uses of devices outside their approved or proposed indication for use in order to determine areas where further pediatric device development could be useful. This recommendation applies to applicants who submit the following applications:

1. Any request for a humanitarian device exemption submitted under section 520(m) of the FD&C Act;

2. Any premarket approval application (PMA) or supplement to a PMA submitted under section 515 of the FD&C Act;
3. Any product development protocol submitted under section 515 of the FD&C Act.

FDA estimates the burden of this collection of information as follows:

Table 1.—Estimated Annual Reporting Burden¹

Description	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Responses	Total Hours
Uses outside approved indication	148	1	148	.5	74
Totals	148		148		74

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents are permitted to submit information relating to uses of the device outside the approved or proposed indication if such uses are described or acknowledged in acceptable sources of readily available information. We estimate that 20 percent of respondents submitting information required by section 515A of the FD&C Act will choose to submit this information and that it will take 30 minutes for them to do so.

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in part 814 (21 CFR part 814), subpart B have been approved under OMB control number 0910-0231 and the collections of information in part 814, subpart H have been approved under OMB control number 0910-0332.

Elsewhere in this issue of the Federal Register, FDA is publishing a proposed rule that requires, under section 515A of the FD&C Act, the submission of readily available

information on any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients.

V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: February 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.